

### **REMARKS**

After entry of this amendment, claims 1-30 are pending, of which claims 6-26 and 29-30 are withdrawn. The claims are amended without prejudice to or disclaimer of Applicants' right to pursue the cancelled subject matter of these and any previously cancelled or amended claims in a later application. The amendments to claim 1 find support *inter alia* in the original claims and in the specification, for example, at paragraphs [0038] and [00040] on pages 8-9, paragraph [00214] on page 47, paragraphs [00229]-[00247] on pages 54-59, and Figures 1-13. The amendments to claim 11 find support *inter alia* in the original claims and in the specification, for example, at paragraph [00176] on page 37, paragraph [00181] on page 28, paragraph [00214] on page 47. No new matter has been added.

The amendment to the specification in the previous response submitted January 17, 2007 adding the paragraph for related applications was inadvertently added in error. The present amendment corrects this error by requesting deletion of this added paragraph. An amendment adding the correct related applications had already been submitted in the amendment and petition of April 29, 2005, which petition was granted in the Decision of October 4, 2005.

Withdrawn method claim 11 drawn to the method of using the product is requested has been amended to depend from the elected product claim or otherwise require all the limitations of the product claims. Furthermore linking claim 21 depends from the elected linking product claim or otherwise requires all the limitations of the product claim. In the event the linking product claim is found allowable, then rejoinder of the method claims and the claims dependent from the elected product claim or otherwise requiring all the limitations of the product claims is requested. MPEP § 821.04(b). Additionally, upon allowance of linking claims 1, 11, and 21, withdrawal of the restriction requirement as to the linked inventions is also requested (Groups I-VI, claims 2-10 for linking claim 1; Groups VII-XIV, claims 12-20 and 29-30 for linking claim 11; Groups XV-XIX, claims 22-25 for linking claim 21; see Official Action mailed March 22, 2006). MPEP §§ 809 and 804.01.

### **Election/Restriction**

Applicants thank the Examiner for rejoining and examining claims 27 and 28 with the claims of Group I.

### **Rejections under 35 U.S.C. § 102**

#### **Lyznik et al.**

Claims 1-4 and 27-28 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Lyznik et al. (hereinafter "Lyznik" ). Applicants respectfully disagree and traverse the rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegall Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631 (Fed. Cir. 1987). "[T]o hold that a prior art reference anticipates a claim, the Board must expressly find that every limitation in the claim was identically shown in the single reference." *Gechter v. Davidson*, 116 F.3d 1454, 1460 (Fed. Cir. 1997).

The Examiner alleges that because the FRTm recognition site is between two homologous sequences, the construct of Lyznik meets all the structure limitations of claim 1. Applicants respectfully disagree. Claim 1 of the present application recites that the recognition sequence for site-directed induction of double-stranded breaks is found between homology sequences A and B. Furthermore, claim 1 recites that the homology sequences A and B are such that they allow for homologous recombination between homology sequences A and B, thus the sequences, *i.e.* the recognition sites, between homology sequences A and B are deleted. Lyznik in contrast teaches that after recombination the FRTm recognition site is still present and not deleted. A recognition sequence which remains in the genome after recombination, as in Lyznik, would allow for further chromosomal rearrangements or deletions and would exclude a further use of the recombination system. See specification at page 3 paragraph [0009]. Thus, contrary to the teaching of Lyznik, the present invention describes a system in which the recognition sites are deleted as the result of the homologous recombination event and a recombination system that

allows for “the repeated, successive application to the same organism.” See page 6 paragraph [0019].

Nevertheless, to expedite prosecution, claim 1 has been amended without prejudice or disclaimer to further characterize the recombination system. In light of the amendments, in the present recombination system of claim 1, the resulting transgenic sequence derived from the transgenic recombination construct does not comprise any recognition site for said enzyme suitable for inducing DNA double-strand breaks. Lyznik teaches that after recombination the construct still has a recognition site present, *i.e.* the FRT<sup>m</sup> recognition site which the Examiner acknowledged as a recognition site for double strand breaks by the FLP recombinase. (See Official Action mailed July 17, 2006, page 4, item 4).

Thus, Lyznik does not teach or suggest all the limitations of the present claims as required for a finding of anticipation. Reconsideration and withdrawal of the rejection is respectfully requested.

Dujon *et al.*

In addition, claims 1-4 and 27-28 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Dujon *et al.* (hereinafter “Dujon”).

The Examiner alleges that because the I-Sce I recognition site is between two homologous sequences and Figure 25B shows homologous recombination of homologous sequences, Dujon meets the limitations the present invention. Applicants respectfully disagree. As explained above, claim 1 of the present application recites that the recognition sequence for site-directed induction of double-stranded breaks is found between homology sequences A and B. Furthermore, because claim 1 recites that the homology sequences A and B are such that they allow for homologous recombination between homology sequences A and B, the sequences, *i.e.* the recognition sites, between homology sequences A and B are therefore deleted. Dujon in contrast teaches that after recombination the I-Sce I recognition site is still present and not deleted. See Figure 25B, result of the recombination to the right of part B 1-3. A recognition sequence which remains in the genome after recombination, as in Dujon, would allow for further chromosomal rearrangements or deletions and would exclude a further use of the recombination

system. See specification at page 3 paragraph [0009]. Thus, contrary to the teaching of Dujon, the present invention describes a system in which the recognition sites are deleted as the result of the homologous recombination event and describes a recombination system that allows for "the repeated, successive application to the same organism." See page 6 paragraph [0019].

Nevertheless, to expedite prosecution, claim 1 has been amended without prejudice or disclaimer to further characterize the recombination system. In light of the amendments, in the present recombination system of claim 1, the resulting transgenic sequence derived from the transgenic recombination construct does not comprise any recognition site for said enzyme suitable for inducing DNA double-strand breaks. Dujon teaches that after recombination the construct still has a I-Sce I recognition site present.

Thus, Dujon does not teach or suggest all the limitations of the present claims as required for a finding of anticipation. Reconsideration and withdrawal of the rejection is respectfully requested.

### **CONCLUSION**

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Should the elected product claim be found allowable, Applicants have requested rejoinder of the linked inventions, claims drawn to method of using the product and claims which depend from or other include all the limitations of the allowed product claim as explained above. Further, Applicants reserve all rights to pursue the non-elected subject matter of the claims in one or more divisional applications, if necessary.

Accompanying this response is a Request for Continued Examination and a petition for a three-month extension of time to and including September 24, 2007 pursuant to 37 CFR § 1.7(a) to respond to the Office Action mailed March 22, 2007 with the required fee authorizations.

Application No. 10/750,891  
Amendment dated September 24, 2007  
Reply to Office Action of March 22, 2007

Docket No.: 13173-00010-US

No further fees are believed due. If any additional fee is due, please charge our Deposit Account No. 03-2775, under Order No. 13173-00010-US from which the undersigned is authorized to draw.

Respectfully submitted,

By 

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